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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,310	07/01/2003	Ryoichi Hashida	3462.1004-000	3981
21005	7590	08/31/2004		
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				
			EXAMINER GALVEZ, JAMES JASON	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/611,310	<b>Applicant(s)</b> HASHIDA ET AL.	
	<b>Examiner</b> J. Jason Galvez	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/1/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Claims 1-53 in the instant application are pending.

#### *Election/Restrictions*

5           Restriction to one of the following inventions is required under 35 U.S.C.  
121:

1.       Claim 1-3 and 31, drawn to a method of screening for a disease,  
classified in class 435, subclass 6.
2.       Claim 4, drawn to polynucleotides, classified in class 536, subclass  
10       23.1.
3.       Claims 5-10, 12 and 32-33, drawn to a method of screening for  
candidate compounds by measuring gene expression, classified in  
class 435, subclass 6.
4.       Claim 11, drawn to a method of screening for candidate  
15       compounds by receptor/ligand binding, classified in class 435,  
subclass 7.1.
5.       Claims 13-19, 25-29, 34-46, and 52-53, drawn to a therapeutic  
agent, classified in class 530, subclass 300.
6.       Claims 20-21, drawn to a transgenic non-human vertebrate,  
20       classified in class 800, subclass 9.
7.       Claims 22-24 and 47-51, drawn to a method of inducing apoptosis,  
classified in class 514, subclass 2.

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8. Claim 30, drawn to a gene expression-inducing ligand classified in class 514, subclass 2.

The inventions are distinct, each from one another because:

- 5        Inventions 1, 3, 4, and 7 are each unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, as they each
- 10        pertain to different methods. Each of the inventions has different starting materials, different modes of operation, different functions, different effects, different objectives, and/or different outcome measures.

- Inventions 1 and 5/6/8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have
- 15        different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable to use together. The methods of invention 1 do not use the products of inventions 5, 6, or 8.

- Inventions 2 and 1/3 are related as product and process of use. The
- 20        inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

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instant case the products of invention 2 can be used another materially different manner, such as the production of recombinant polypeptides.

Inventions 2, 5, 6, and 8 are each unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides, polypeptides, and transgenic non-human vertebrates are all physically and functionally distinct chemical entities that have different structures, functions, and activities.

Inventions 2 and 4/7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The products of invention 2 are not used in the methods of inventions 4 or 7.

Inventions 3 and 5 are related as a method of screening and products identified. In the instant case the inventions are distinct because the products identified can be accomplished by another materially different method, such as binding assays.

Inventions 3 and 6/8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not

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disclosed as capable of use together. The methods of invention 3 do not use the products of inventions 6 or 8.

Inventions 4 and 5 are related as a method of screening and products identified. In the instant case the inventions are distinct because the products  
5 identified can be accomplished by another materially different method, such as polynucleotide and/or polypeptide expression assays.

Inventions 4 and 6/8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §  
10 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The methods of invention 4 do not use the product of inventions 6 or 8.

Inventions 5 and 7 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be  
15 shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product, such as free radicals.

20 Inventions 6 and 7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not

disclosed as capable of use together. The products of invention 6 are not used in the methods of invention 7.

Inventions 7 and 8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have  
5 different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The methods of invention 7 do not use the products of invention 8.

The examiner has required restriction between the product and process  
10 claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable**  
15 **product** will be entered as a matter of right if the amendment is presented prior to final rejections or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the  
20 product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and

5 Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoiner in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the  
10 product claims. **Failure to do so may result in a loss of the right to rejoiner.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and  
15 have acquired a separate status in the art as shown by their different classification, separate search requirement, and divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably  
20 distinct species of the claimed invention:

A. Nuclear orphan receptors: TR3 and TINUR

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no



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generic claim is finally held to be allowable. Currently, claim 1 (for example) is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a  
5 listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form  
10 or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence  
15 now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably  
20 distinct species of the claimed invention:

B. TR3 or TINUR ligands listed in claim 17 and Tables 14-49.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no

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generic claim is finally held to be allowable. Currently, claims 16 and 18 (for example) are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a  
5 listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form  
10 or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence  
15 now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

20 Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

**If Applicant elects Groups 1-6, or 7, a species election from Group A (Nuclear orphan receptors) is required. In addition, if Applicant elects Group 5, a species election from Group A (Nuclear orphan receptors) and Group B (TR3 or TINUR ligands) is required.**

5

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D.** whose telephone number is **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

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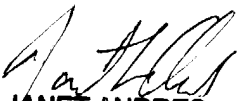
The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained

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from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center

5 (EBC) at **866-217-9197** (toll-free).

JJG  
8/25/2004

  
**JANET ANDRES**  
**PRIMARY EXAMINER**